K072286

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SECTION 6

510(k) SUMMARY

NOV 2 0 2007

Date Prepared: November 4, 2007

Company Name and Address

Aspect Medical Systems, Inc.
One Upland Road
Norwood, MA 01532

Contact Person: Vikram Verma
Manager, RA/QA
Telephone (direct dial): (617) 559-7134
Fax #: (617) 559-7948

Device Name

Proprietary Name: Aspect Medical Systems BIS EEG VISTA Monitor System, VISTA

Common Name: EEG Monitor

Proprietary Name: Aspect Medical Systems BISx

Common Name: EEG Monitor

Classification

Electroencephalograph (EEG) monitors have been classified by the Neurological Devices Panel as Class II devices (21 CFR 882.1400)

Predicate Device

Aspect Medical System's A-3000 EEG Monitor with BIS (#K052362), Spectral EEG Monitor A1000 (# K963644), Aspect Medical Systems BIS EEG Monitor VIEW (#K062613), Aspect Medical System's BISx4 (#K052981), Aspect Medical System's BISx (#K040183)

Device Description:

A. BIS EEG VISTA Monitor System:

The BIS EEG VISTA Monitor System, is comprised of the BISx4, the VISTA Monitor, and associated cables. When the System is connected to a BIS Sensor (which is applied to the patient's forehead, acquires EEG signals from the brain, and is 510(k) cleared) the monitor displays 2 channels of EEG. When the System is connected to a BIS Bilateral Sensor (also 510(k) cleared), the monitor displays 4 channels of EEG.

The BISx4 houses the digital signal converter as well as the BIS algorithm (it has no display or user interface), and it performs the computations necessary to produce the Bispectral Index (BIS). It also calculates SQI, EMG, Burst count and Suppression Ratio. The BISx4 may be distributed to business partners that have the ability to display BIS on their patient monitors.

The Monitor displays a maximum of 4 channels of EEG, as well as SQI, EMG, Burst Count, Suppression Ratio and a BIS value. The BIS value is acquired using 2 channels of EEG. The Monitor has secondary trend and trend review screens, as well as results of self tests.

In addition to the above, when connected to a Bilateral Sensor, the System provides additional capability as follows:

BISx4 calculates DSA, Asymmetry, sBIS, and sEMG. The Monitor displays DSA, Asymmetry, sBIS, and sEMG numerically and graphically.

B. BISx device:

The BISx is a component that processes up to 2 channels of EEG and computes BIS and other EEG parameters (same as the cleared BISx device). The BISx connects to Aspect sensors on one side and the Aspect Monitor or OEM patient monitoring systems on the other, allowing them to display BIS on their integrated patient monitoring systems. The OEMs are responsible for the regulatory pathway to integrate the BISx in their systems.

The software is a moderate level of concern. This submission is updating the indications for use statement for the BISx device, to reflect the addition of clinical benefits added at FDA request to the BIS EEG VIEW Monitor, 510(k) (K#062613, recently cleared on 6/18/07). No change is being made to the cleared BISx device (#K040183).

Indications for use for BIS EEG Monitor System (VISTA Monitor and BISx4), and the BISx device:

A. Indications for use for BIS EEG Monitor System (VISTA Monitor and BISx4):

The BIS EEG VISTA Monitor System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in their proper use. The system, and all its associated parameters, is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS Index, one of the VISTA Monitor output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of the BIS Index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

B. Indications for use for BISx device:

The BISx is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in their proper use. The BISx, and all its associated parameters, is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS Index, one of the BISx output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of the BIS Index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

Summary of Technological Characteristics Compared to Predicate Device

The BIS EEG VISTA Monitor System has the same intended use and fundamental scientific technology as the predicate device, BIS EEG Monitor, VIEW. The BIS EEG System, VISTA with updated software features, offers the same features and parameters that were found in one of the predicate devices or merely displays them in additional ways.

The BISx device has the same intended use and fundamental scientific technology as the predicate device, BISx (K040183). No modifications have been made to this device.

Summary of Testing

The following tests/analyses have been completed for the BIS EEG VISTA Monitor System:

- Software Validation
- Hazard Analysis and Risk Assessment

Results indicate the device meets its performance specifications and validation test requirements, and is safe for its intended use.

Conclusion:

Based on the above, Aspect Medical Systems believes the VISTA System, and the BISx device are substantially equivalent to the predicate devices, and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aspect Medical Systems Inc.
c/o Mr. Vikram Verma
Manager, RA/QA
One Upland Road
Norwood, MA 02062

APR - 9 2012

Re: K072286
Trade/Device Name: BIS EEG Vista Monitor System and BISx
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, OLT, ORT
Dated (Date on orig SE ltr): November 4, 2007
Received (Date on orig SE ltr): November 6, 2007

Dear Mr. Verma:

This letter corrects our substantially equivalent letter of November 20, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)	**K072286**
Device Name	BISx

Indications for Use

The BISx is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in their proper use. The BISx, and all its associated parameters, is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS Index, one of the BISx output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of the BIS Index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

Mark A Miller

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072286

Prescription Use __X_____ AND/OR Over-The Counter Use

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)